

K963930

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510(k) Summary
CardioThoracic Systems, Inc.
CTS MIDCAB™ /SVH™ Bipolar Scissors
510(k) Notification K 963930

GENERAL INFORMATION

Manufacturer: CardioThoracic Systems, Inc.
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Cupertino, California
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Est. Reg. No. (awaiting issuance)

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DEVICE DESCRIPTION

Classification: Class II

Trade Name: CTS MIDCAB™/SVH™ Bipolar Scissors

Generic/Common Name: Electrosurgical cutting and coagulation device and accessories
21CFR878.4400

PREDICATE DEVICES

- (1) Symbiosis Bipolar Scissors
- (2) Everest Medical Bipolar Scissors
- (3) Valley Forge Bi-Tech Bipolar Coagulator/Cutting System
- (4) Valleylab Force 2 and Force 4 Electrosurgical Generators

INTENDED USE

The CTS MIDCAB/SVH Bipolar Scissors is intended to cut tissue and control bleeding through coagulation, in general and cardiothoracic surgery, including minimally invasive direct coronary artery bypass ("MIDCAB") and saphenous vein harvesting procedures.

PRODUCT DESCRIPTION

The CTS MIDCAB/SVH Bipolar Scissors is an electrosurgical instrument which consists of a pair of scissor blades which are connected to a handle instrument and an electrosurgical generator. Electric current flows from the electrode to the stainless steel cutting surface of the blades and from the stainless steel cutting surface of one blade to the stainless steel cutting surface of the other blade. The flow of the electric current down the electrode is controlled by the power generator. The overall length of the device, which consists of the handle, tube and blades, is approximately 13 inches. The power cord connecting the handle to the power control unit is approximately 120 inches. The blades are approximately 0.5 inches in length.

The surgeon places the opened scissors across the tissue to be cut and depresses the actuation lever while moving the scissors forward against the tissue. By energizing the power control unit on the actuation lever, the surgeon can simultaneously cut and coagulate the target tissue.

Alternately, the power control unit may be controlled via a foot pedal. The surgeon can vary the current flow rate according to the tissue and the amount of bleeding encountered. The power setting used for the CTS Bipolar Scissors is 20-30 watts.

The CTS Bipolar Scissors is provided sterile, nonpyrogenic and for single use.

SUBSTANTIAL EQUIVALENCE

The CTS MIDCAB/SVH Bipolar Scissors is substantially equivalent to the above identified predicate devices. The CTS Bipolar Scissors is substantially equivalent to the predicate devices with regard to intended use, function, physical characteristics, materials and sterilization method. The CTS, Symbiosis and Everest devices are all bipolar scissors which cut tissue and coagulate soft tissue through the use of bipolar technology. All three devices are connected to the same or similar electrosurgical generators and use similar power ranges for operation.

SUMMARY

As contained in this 510(k) summary, the CTS MIDCAB/SVH is substantially equivalent to the predicate devices identified.